IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois Corporation, and CENTRAL GLASS COMPANY LTD., a Japanese Corporation	JUDGE RONALD GUZMAN
Plaintiffs,	**01 C 1867**
v.	**Judge** _____
BAXTER PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, and BAXTER HEALTHCARE, CORP. a Delaware Corporation	**Case No.** _____
	MAGISTRATE JUDGE ASHMAN
Defendants.	**JURY TRIAL DEMANDED**

COMPLAINT

Abbott Laboratories ("Abbott") and Central Glass Company Ltd. ("Central Glass") by and through their attorneys, hereby complain against the Defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corp. (collectively "Baxter") as follows.

NATURE OF THE ACTION

1. This is a patent infringement action involving sevoflurane, Abbott's anesthetic inhalant, which it sells under the trademark Ultane®. This anesthetic inhalant is used in the induction and maintenance of general anesthesia in adult and pediatric patients. Abbott filed a New Drug Application and received authorization from the Federal Food and Drug Administration ("FDA") to market and sale sevoflurane in 1995.

THE PARTIES

2. Plaintiff Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Abbott is a diversified health care company.

3. Plaintiff Central Glass is a Japanese corporation with its principal place of business in Tokyo, Japan.

4. Defendant Baxter Pharmaceutical Products, Inc. is a Delaware corporation with its principal place of business in New Jersey. Baxter Pharmaceutical Products, Inc. is a wholly owned subsidiary of Baxter Healthcare Corp.

5. Defendant Baxter Healthcare Corp. is a Delaware corporation with its principal place of business in Deerfield, Illinois.

JURISDICTION AND VENUE

6. Jurisdiction is proper under 35 U.S.C. §§ 271(a), (b), and (e) and 281. Jurisdiction also is proper under 28 U.S.C. §§ 1331, 1332, and 1338(a).

7. Venue is proper under 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

8. This Court has personal jurisdiction over the Defendants because, among other things, Baxter does business and transacts business in this judicial district.

BACKGROUND FACTS

9. Abbott was the first company to bring sevoflurane to market in the United States and did so in approximately June 1995. From about June 1995 Abbott has sold sevoflurane in glass bottles. Abbott also currently sells sevoflurane in its PEN container.

10. In 1996, Plaintiffs learned that sevoflurane degraded when the sevoflurane reacted with a Lewis Acid from an external source. Plaintiffs discovered, among other things, that the addition of an effective amount of a Lewis Acid inhibitor, such as water, could inhibit the degradation of sevoflurane in the presence of Lewis Acids.

11. In January 1997, the Plaintiffs filed for a patent relating to their discoveries. On November 23, 1999, the United States Patent and Trademark Office ("PTO")

duly and legally issued United States Patent No. 5,990,176 ("the '176 Patent"), entitled "Fluoroether Compositions and Methods For Inhibiting Their Degradation In the Presence of a Lewis Acid". A true and correct copy of the '176 Patent is attached hereto as Exhibit A. Plaintiffs own all rights and interests in the '176 Patent which patent has properly been listed in the FDA Orange Book.

COUNT I –INFRINGEMENT OF UNITED STATES PATENT NO. 5,990,176

12. Plaintiffs repeat and reallege the allegations contained in paragraphs 1-11 of their Complaint as if those allegations were set forth verbatim herein.

13. Baxter intends to market and sell a sevoflurane product that infringes upon the '176 Patent. Baxter filed with the FDA in Rockville, Maryland an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use and sale of sevoflurane. Baxter subsequently filed an Amendment to its original ANDA filing to obtain approval to market and sell yet another generic version of sevoflurane before the expiration date of the '176 Patent. Baxter also filed with its Amendment with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '176 Patent are not infringed and are invalid.

14. On or about January 31, 2001, Baxter sent a letter to Abbott and Central Glass stating that the sender represented Baxter and was sending the letter on behalf of Baxter to advise Abbott that Baxter had filed an amended ANDA with respect to sevoflurane and was providing information to Abbott pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

15. Abbott has been advised through a ¶ 4 certified letter from Baxter dated January 31, 2001 that sevoflurane in a non-glass container is the product and the accused device in this case. The non-glass container is said to be effective in controlling for the unexpected

presence of Lewis Acids. The Abbott patent is not limited to a glass container. Glass is one example of a container. Baxter's representations that it will have a measurable limited and controlled amount of water in a non-glass container to effectively offset the unexpected presence of Lewis Acid infringes at least Claim 1 of the '176 patent.

16. Under 35 U.S.C. §§ 271(e)(2)(A), Baxter's submission to the FDA of an amended ANDA and a certification letter pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval for the commercial manufacture, use and sale of sevoflurane before the expiration of the '176 Patent was an act that infringes the claims of the '176 Patent.

WHEREFORE, Plaintiffs pray:

A. That U.S. Patent No. 5,990,176 be judged valid, enforceable, and infringed by Defendants;

B. That the Court declare this an exceptional case and award Plaintiffs their reasonable costs, expenses, and attorneys' fees pursuant to 35 U.S.C. § 285; and

C. That the Court award such other and further relief which this Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand trial by jury for all issues triable of right by jury in this action.

Respectfully submitted,

ABBOTT LABORATORIES
CENTRAL GLASS CO., LTD.

Dated: March 15, 2001 By: _____
One of Their Attorneys

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US005990176A

United States Patent [19]

Bieniarz et al.

[11] Patent Number: 5,990,176

[45] Date of Patent: *Nov. 23, 1999

[54] FLUOROETHER COMPOSITIONS AND METHODS FOR INHIBITING THEIR DEGRADATION IN THE PRESENCE OF A LEWIS ACID

[75] Inventors: **Christopher Bieniarz**, Highland Park; **Steve H. Chang**, Gurnee; **Keith R. Cromack**, Lake Bluff; **Shuyen L. Huang**, Riverwoods, all of Ill.; **Toshikazu Kawai**, Tsurugashima; **Manami Kobayashi**, Miyoshimachi, both of Japan; **David Loffredo**, Elmhurst, Ill.; **Rajagopalan Raghavan**, Grayslake, Ill.; **Earl R. Speicher**, Buffalo Grove, Ill.; **Honorate A. Stelmach**, Lake Forest, Ill.

[73] Assignees: **Abbott Laboratories**, Abbott Park, Ill.; **Central Glass Company Ltd.**, Tokyo, Japan

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: **08/789,679**

[22] Filed: **Jan. 27, 1997**

[51] **Int. Cl.**[6] **A61K 31/08**; C07C 43/12

[52] **U.S. Cl.** **514/722**; 568/683; 568/684

[58] **Field of Search** 514/722, 816; 568/683, 684

[56] **References Cited**

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XP00206144; Dressing J., Sprenger A., Kieviet O.S.: "Repertorium 94/95", 1994, NL., S–Gravenhage, SDU, The Hague.

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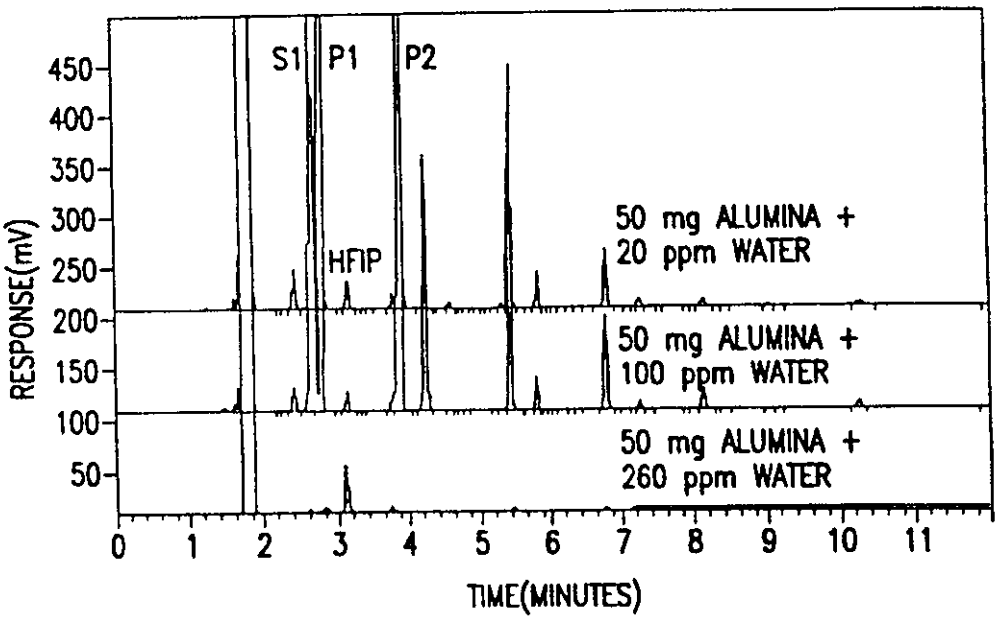
Primary Examiner—Alan L. Rotman
Assistant Examiner—Charanjit S. Aulakh
Attorney, Agent, or Firm—Brian R. Woodworth

[57] **ABSTRACT**

The present invention relates to an anesthetic composition containing a fluoroether compound and a physiologically acceptable Lewis acid inhibitor. This composition exhibits improved stability and does not readily degrade in the presence of a Lewis acid.

10 Claims, 5 Drawing Sheets


S1
P1
P2
HFIP
50 mg ALUMINA +
20 ppm WATER
50 mg ALUMINA +
100 ppm WATER
50 mg ALUMINA +
260 ppm WATER
RESPONSE(mV)
450
400
350
300
250
200
150
100
50
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1
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6
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8
9
10
11
TIME(MINUTES)

FIG.1

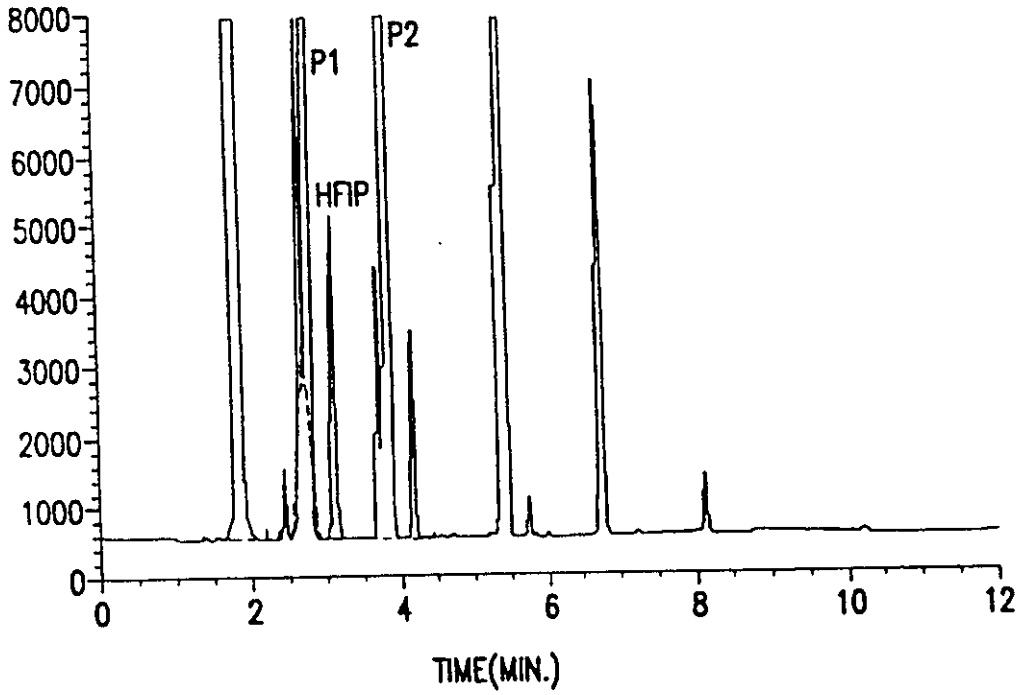

8000
7000
6000
5000
4000
3000
2000
1000
0
P1
P2
HFIP
0
2
4
6
8
10
12
TIME(MIN.)

FIG.2

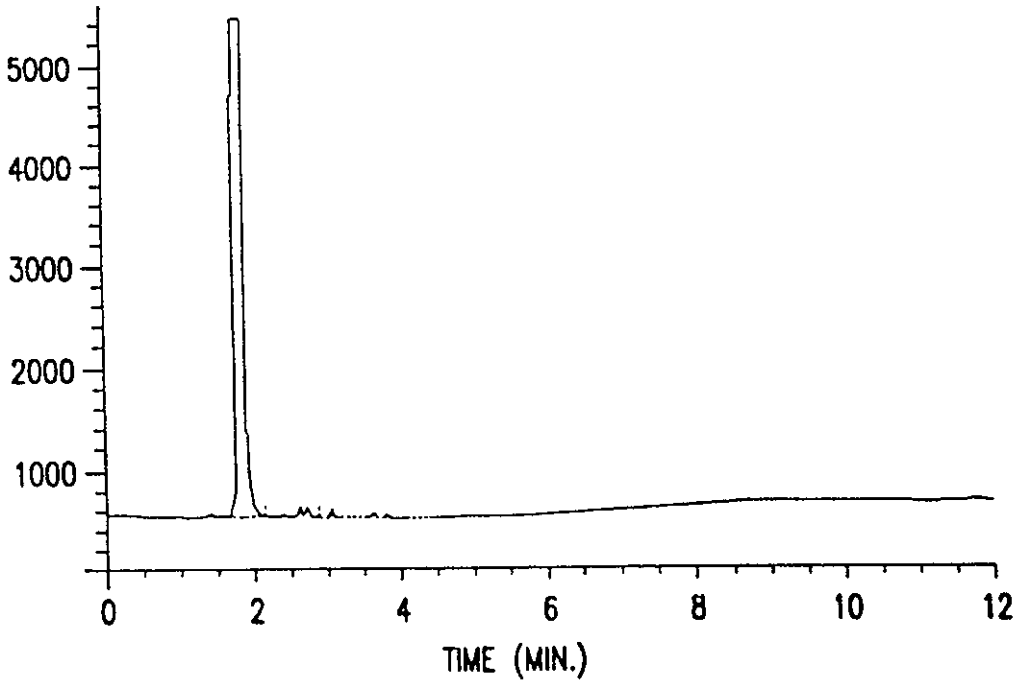
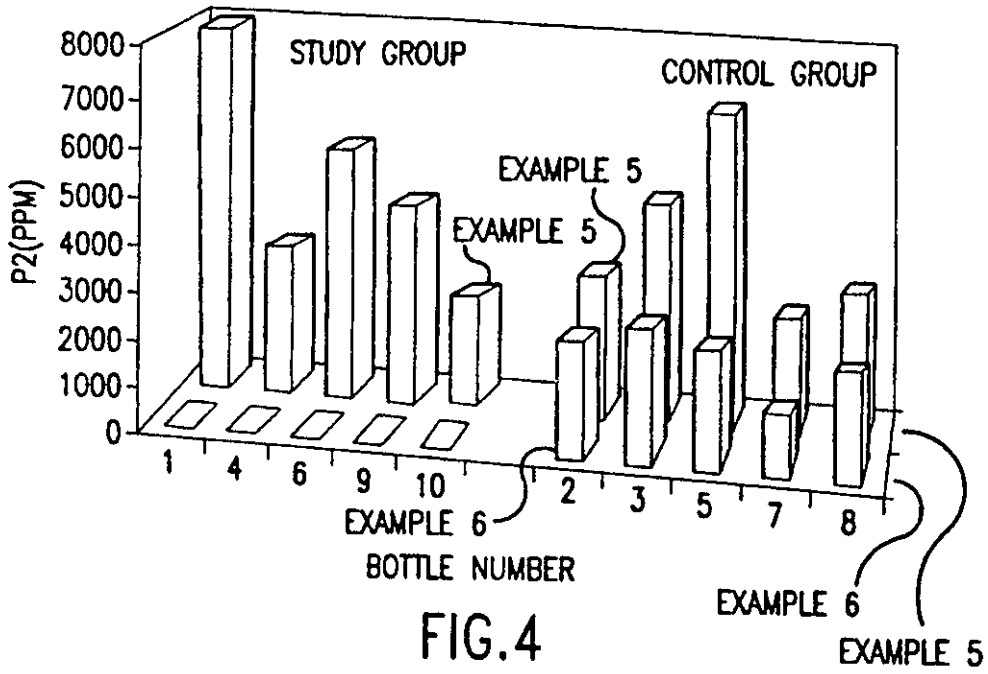


FIG.3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6000
5000
4000
3000
2000
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0
P2(PPM)
STUDY GROUP
CONTROL GROUP
EXAMPLE 5
EXAMPLE 5
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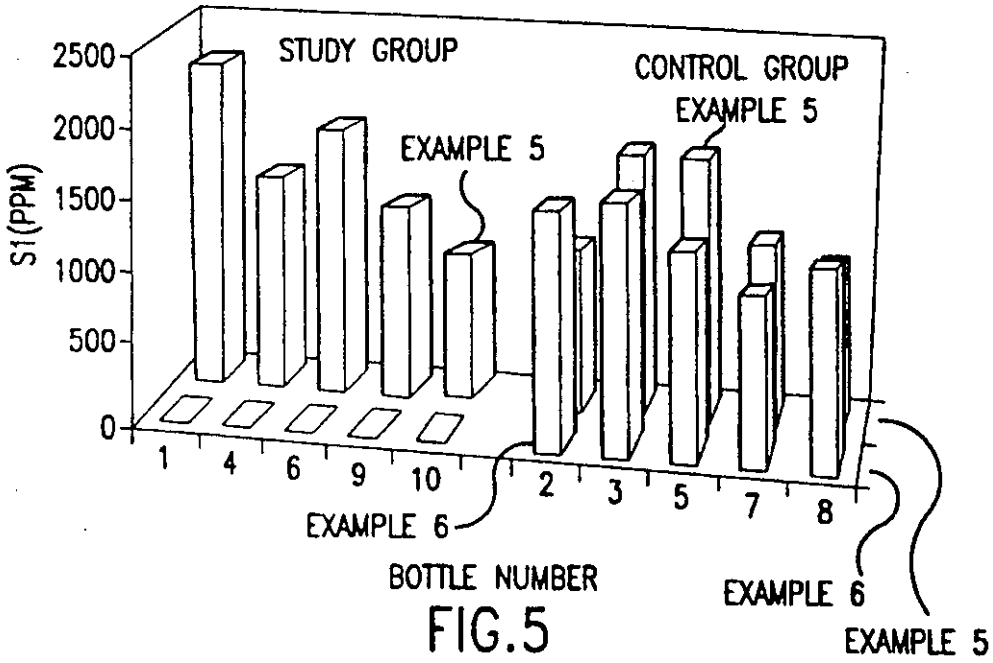
6
9
10
2
3
5
7
8
EXAMPLE 6
BOTTLE NUMBER
EXAMPLE 6
EXAMPLE 5

FIG.4


STUDY GROUP
CONTROL GROUP
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EXAMPLE 5
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1500
1000
500
0
S1(PPM)
1
4
6
9
10
2
3
5
7
8
EXAMPLE 6
BOTTLE NUMBER
EXAMPLE 6
EXAMPLE 5

FIG.5

FLUOROETHER COMPOSITIONS AND METHODS FOR INHIBITING THEIR DEGRADATION IN THE PRESENCE OF A LEWIS ACID

TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to stable, anesthetic fluoroether compositions that do not degrade in the presence of a Lewis acid. The present invention also relates to a method of inhibiting the degradation of fluoroethers in the presence of Lewis acids.

BACKGROUND OF THE INVENTION

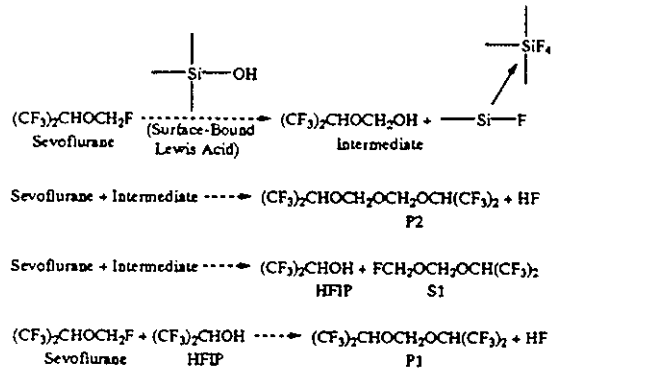
Fluoroether compounds are commonly employed as anesthetic agents. Examples of fluoroether compounds used as anesthetic agents include sevoflurane (fluoromethyl-2,2,2-trifluoro-1-(trifluoromethyl)ethyl ether), enflurane ((±)-2-chloro-1,1,2-trifluoroethyl difluoromethyl ether), isoflurane (1-chloro-2,2,2-trifluoroethyl difluoromethyl ether), methoxyflurane (2,2-dichloro-1,1-difluoroethyl methyl ether), and desflurane ((±)-2-difluoromethyl 1,2,2,2-tetrafluoroethyl ether).

Although fluoroethers are excellent anesthetic agents, it has been discovered that some fluoroethers experience stability problems. More specifically, it has been determined that certain fluoroethers, in the presence of one or more Lewis acids, degrade into several products including potentially toxic chemicals such as hydrofluoric acid. Hydrofluoric acid is toxic by ingestion and inhalation and is highly corrosive to skin and mucous membranes. Thereupon, the degradation of fluoroethers to chemicals such hydrofluoric acid is of great concern to the medical community.

Degradation of fluoroethers has been found to occur in glass containers. The degradation of fluoroethers in glass containers is believed to be activated by trace amounts of Lewis acids present in the container. The source of the Lewis acids can be aluminum oxides, which are a natural component of glass. When the glass wall becomes altered or etched in some manner, the aluminum oxide become exposed and come into contact with the contents of the container. The Lewis acids then attack the fluoroether and degrade it.

For example, when the fluoroether sevoflurane is contacted with one or more Lewis acids in a glass container under anhydrous conditions, the Lewis acid initiates the degradation of sevoflurane to hydrofluoric acid and several degradation products. The degradation products of sevoflurane are hexafluoroisopropyl alcohol, methyleneglycol bishexafluoroisopropyl ether, dimethyleneglycol bishexafluoroisopropyl ether and methyleneglycol fluoromethyl hexafluoroisopropyl ether. The hydrofluoric acid proceeds to further attack the glass surface and expose more of the Lewis acid on the glass surface. This results in further degradation of sevoflurane.

The degradation mechanism of sevoflurane in the presence of a Lewis acid can be illustrated as follows:



Abbv.	Compound Name	Structure
HFIP	hexafluoroisopropyl alcohol	$(CF_3)_2CHOH$
P1	methyleneglycol bishexafluoroisopropyl ether	$(CF_3)_2CHOCH_2OCH(CF_3)_2$
P2	dimethyleneglycol bishexafluoroisopropyl ether	$(CF_3)_2CHOCH_2OCH_2OCH(CF_3)_2$
S1	methyleneglycol fluoromethyl hexafluoroisopropyl ether	$(CF_3)_2CHOCH_2OCH_2F$

Therefore, a need exists in the art for a stable anesthetic composition containing fluoroether compounds that does not degrade in the presence of a Lewis acid.

SUMMARY OF THE INVENTION

The present invention involves a stable anesthetic composition that contains a fluoroether compound having an alpha fluoroether moiety having added thereto an effective stabilizing amount of a Lewis acid inhibitor . The preferred fluoroether compound is sevoflurane and the preferred Lewis acid inhibitor is water. The composition can be prepared by adding the Lewis acid inhibitor to the fluoroether compound, by adding the fluoroether compound to the Lewis acid inhibitor, or by washing a container with the Lewis acid inhibitor and then adding the fluoroether compound.

The present invention also involves a method for stabilizing a fluoroether compound having an alpha fluoroether moiety. The method involves adding an effective stabilizing amount of a Lewis acid inhibitor to the fluoroether compound to prevent the degradation of the fluoroether compound by a Lewis acid. The preferred fluoroether compound is sevoflurane and the preferred Lewis acid inhibitor is water.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows a chromatogram demonstrating that in the presence of the same amount of aluminum oxide (50 mg), the degradation of sevoflurane decreases with increasing amounts of water. The identified degradation products of sevoflurane shown in FIG. 1 are hexafluoroisopropyl alcohol (HFIP), methyleneglycol bishexafluoroisopropyl ether (P1), dimethyleneglycol bishexafluoroisopropyl ether (P2) and methyleneglycol fluoromethyl hexafluoroisopropyl ether (S1).

FIG. 2 depicts a chromatogram showing the degradation of sevoflurane after heating in an autoclave at 119° C. for 3 hours.

FIG. 3 depicts a chromatogram showing the effects of water on the inhibition of the degradation of sevoflurane after heating in an autoclave at 119° C. for 3 hours.

FIG. 4 shows a bar graph comparing the sevoflurane degradant P2 in activated type III amber glass bottles from Examples 5 and 6. The graph demonstrates that the degradation of sevoflurane is inhibited by the addition of 400 ppm of water.

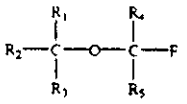
FIG. 5 shows a bar graph comparing the sevoflurane degradant S1 in activated type III amber glass bottles from Examples 5 and 6. The graph shows that the degradation of sevoflurane is inhibited by the addition of 400 ppm of water.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a stable, anesthetic composition that does not degrade in the presence of a Lewis acid. The present invention also relates to methods of preparing said anesthetic composition.

The anesthetic composition of the present invention contains at least one fluoroether compound. The fluoroether compound used in the composition corresponds to Formula I, below.

(I)



In Formula I, each R_1; R_2; R_3; R_4; and R_5 can independently be a hydrogen, halogen, an alkyl group having from 1 to 4 carbon atoms (C_1–C_4 alkyl), or a substituted alkyl having from 1 to 4 carbon atoms (C_1–C_4 substituted alkyl). In the preferred embodiment of Formula I, R_1 and R_3 are each the substituted alkyl CF_3 and R_2, R_4 and R_5 are each a hydrogen.

As used herein, the term "alkyl" refers to a straight or branched chain alkyl group derived from saturated hydrocarbons by the removal of one hydrogen atom. Examples of alkyl groups include methyl, ethyl, n-propyl, isopropyl, n-butyl, sec-butyl, iso-butyl, tert-butyl, and the like. As used herein, the term "substituted alkyl" refers to an alkyl group substituted by one or more groups such as halogen, amino, methoxy, difluoromethyl, trifluoromethyl, dichloromethyl, chlorofluoromethyl, etc. As used herein, the term "halogen" refers to one of the electronegative elements of group VIIA of the periodic table.

The fluoroether compounds having the Formula I contain the alpha fluoroether moiety —C—O—C—F— Lewis acids attack this moiety which results in the degradation of the fluoroether to various degradation products and toxic chemicals.

Examples of fluoroether compounds of Formula I that can be used in the present invention are sevoflurane, enflurane, isoflurane, methoxyflurane and desflurane. The preferred fluoroether compound for use in the present invention is sevoflurane.

Methods for making the fluoroether compounds having Formula I are well known in the art and can be used in preparing the composition of the present invention. For example, sevoflurane can be prepared using the methods described in U.S. Pat. No. 3,689,571 and U.S. Pat. No. 2,992,276 herein incorporated by reference.

The composition of the present invention contains a total of from about 98% w/w to about 100% w/w of a fluoroether compound having the Formula I. Preferably, the composition contains at least 99.0% w/w of the fluoroether compound.

The anesthetic composition of the present invention also contains a physiologically acceptable Lewis acid inhibitor. As used herein, "Lewis acid inhibitor" refers to any compound that interacts with the empty orbital of a Lewis acid thereby blocking the potential reaction sites of the acid. Any physiologically acceptable Lewis acid inhibitor can be used in the composition of the present invention. Examples of Lewis acid inhibitors that can be used in the present invention include water, butylated hydroxytoluene (1,6-bis(1,1-dimethyl-ethyl)-4-methylphenol), methylparaben (4-hydroxybenzoic acid methyl ester), propylparaben (4-hydroxybenzoic acid propyl ester), propofol (2,6-diisopropyl phenol) and thymol (5-methyl-2-(1-methylethyl)phenol).

The composition of the present invention contains an effective stabilizing amount of a Lewis acid inhibitor. It is believed that the effective stabilizing amount of Lewis acid inhibitor that can be used in the composition is about 0.0150% w/w (water equivalent) to about the saturation level of the Lewis acid inhibitor in the fluoroether compound. As used herein, the term "saturation level" means the maximum solubility level of the Lewis acid inhibitor in the fluoroether compound. It will be appreciated that the saturation level may be temperature dependent. The saturation level also will depend on the particular fluoroether compound and the particular Lewis acid inhibitor being used in the composition. For example, when the fluoroether compound is sevoflurane and the Lewis acid inhibitor is water, the amount of water employed to stabilize the composition is believed to be from about 0.0150% w/w to about 0.14% w/w (saturation level). It should be noted, however, that once the composition is exposed to Lewis acids, the amount of Lewis acid inhibitor in the composition may decrease as the Lewis acid inhibitor reacts with the Lewis acid to prevent the unwanted degradative reaction of Lewis acid inhibitor with the composition.

The Lewis acid inhibitor preferred for use in the composition of the present invention is water. Purified or distilled water or a combination of both can be used. As stated earlier, the effective amount of water that can be added to the composition is believed to be about 0.0150% w/w to about 0.14% w/w, and is preferably about 0.0400% w/w to about 0.0800% w/w. For any other Lewis acid inhibitor, a molar equivalent based upon moles of water should be used.

When the fluoroether compound is exposed to a Lewis acid, the physiologically acceptable Lewis acid inhibitor present in the composition donates electrons to the empty orbital of the Lewis acid and forms a covalent bond between the inhibitor and the acid. Thereupon, the Lewis acid is prevented from reacting with the alpha fluoroether moiety of the fluoroether and degrading the fluoroether.

The composition of the present invention can be prepared in several ways. In one aspect, a container, such as a glass bottle, is first washed or rinsed with the Lewis acid inhibitor and then filled with the fluoroether compound. Optionally, the container may be partially dried after the washing or rinsing. Once the fluoroether is added to the container, the container is sealed. As used herein, the term "partially dried" refers to an incomplete drying process that leaves a residual of a compound on or in the container being dried. Also as used herein, the term "container" refers to a receptacle made from glass, plastic, steel or other material that can be used for holding goods. Examples of containers include bottles, ampules, test tubes, beakers, etc.

In another aspect, the Lewis acid inhibitor is added to a dried container prior to filling the container with the fluoroether compound. Once the Lewis acid inhibitor has been added, the fluoroether compound is added to the container. Alternatively, the Lewis acid inhibitor may be added directly to a container already containing the fluoroether compound.

In another aspect, the Lewis acid inhibitor may be added to a container filled with the fluoroether compound under humid conditions. For example, water can be added to a container filled with the fluoroether compound by placing the container in a humidity chamber for a sufficient amount of time to allow the water to accumulate in the container.

The Lewis acid inhibitor can be added to the composition at any appropriate point in the manufacturing process, e.g., at the final manufacturing step before filling into shipping containers, e.g., 500 liter shipping container. Appropriate quantities of the composition can be dispensed from the container and packaged in containers of more suitable size for use in the industry, such as 250 mL glass bottles. Additionally, small quantities of the composition containing appropriate amounts of the Lewis acid inhibitor can be used to wash or rinse containers to neutralize any Lewis acids that might be present in the container. Once the Lewis acids have been neutralized, the container may be emptied and additional quantities of the fluoroether composition added to the container prior to sealing the container.

By way of example, but not of limitation, examples of the present invention will now be given.

EXAMPLE 1

Activated Alumina as a Lewis Acid

Type III glass consists mainly of silicon dioxide, calcium oxide, sodium oxide and aluminum oxide. Aluminum oxide is a known Lewis acid. The glass matrix is normally inert to sevoflurane. However, under certain conditions (anhydrous, acidic), the glass surface can be attacked or altered, exposing sevoflurane to active Lewis acid sites such as aluminum oxide.

The effect of water on the degradation of sevoflurane was studied by adding various amounts of activated alumina to 20 ml of sevoflurane containing the following three levels of moisture: 1) 20 ppm water—measured water, no additional water added; 2) 100 ppm—spiked; and 3) 260 ppm water—spiked. Table 1 below shows the experimental matrix.

TABLE 1

	1	2	3
A	50 mg Al_2O_3 20 ppm Water	50 mg Al_2O_3 100 ppm Water	50 mg Al_2O_3 260 ppm Water
B	20 mg Al_2O_3 20 ppm Water	20 mg Al_2O_3 100 ppm Water	20 mg Al_2O_3 260 ppm Water
C	10 mg Al_2O_3 20 ppm Water	10 mg Al_2O_3 100 ppm Water	10 mg Al_2O_3 260 ppm Water

It will be appreciated that 20 ppm Water is equivalent to 0.0022% w/w Water. The samples were placed at 60° C. and analyzed by gas chromatography after 22 hours. FIG. 1 shows that in the presence of the same amount of aluminum oxide (50 mg) that the degradation of sevoflurane decreases with increasing amounts of water (Row A from Table 1). A similar trend was observed for 20 mg and 10 mg of aluminum oxide (Rows B and C).

EXAMPLE 2

Degradation in Ampules of Sevoflurane by Heat with and without the Addition of Water

Approximately 20 mL of sevoflurane was added to a 50 mL Type I clear ampule and approximately 20 mL of sevoflurane and 1300 ppm of water was added to a second ampule. Both ampules were flame-sealed and then autoclaved at 195° C. for three hours. The contents of the two ampules were then analyzed by gas chromatography. FIG. 2 shows that the sevoflurane in the first ampule degraded. FIG. 3 shows that the sevoflurane in the second ampule did not degrade as a result of the Lewis acid inhibitor, namely the added water.

EXAMPLE 3

Degradation of Sevoflurane in Ampules using Water-Spiked Studies (109 ppm to 951 ppm)

Type I clear glass ampules were used to study the effect of various levels of water in inhibiting the degradation of sevoflurane. Approximately 20 mL of sevoflurane and different levels of water ranging from about 109 ppm to about 951 ppm were added to each ampule. The ampules were then sealed. A total of ten ampules were filled with sevoflurane and varying amounts of water. Five of the ampules were included in Set A and the other five ampules were included in Set B. The ampules were then autoclaved at 119° C. for three hours. Samples in Set A were placed on a mechanical shaker overnight to allow the moisture to coat the glass surface. Samples in Set B were prepared without equilibrating the water with the glass surface. Several control samples were al so prepared. Two non-autoclaved ampules (Control Ampule 1 and Control Ampule 2) and a bottle (Control bottle) were each filled with 20 mL of sevoflurane. No water was added to any of the control samples. Also, the controls samples were not shaken overnight. The levels of hexafluoroisopropanol (HFIP) and total degradants (including methyleneglycol bishexafluoroisopropyl ether, dimethyleneglycol bishexafluoroisopropyl ether, methyleneglycol fluoromethyl hexafluoro isopropyl ether) were measured by gas chromatography. The results are shown below in Table 2.

TABLE 2

Sample	Total Moisture Calculated (ppm)	pH	HFIP (ppm)	Total Degradants without HFIP (ppm)
Control, Bottle		6.0	6	57
Control, Ampule 1, RT		3.0	7	50
Control, Ampule 2, RT		4.0	6	51
Set A (Shaken Overnight)				
1	109	0	1.525	201614
2	206	0	2.456	105518
3	303	0	4.027	127134
4	595	5.0	7	82
5	951	5.0	12	84
Set B (Not Shaken)				
1	109	0	1.936	195364
2	206	0	3.390	170869
3	303	0	5.269	101845
4	595	6.0	21	107
5	951	6.0	10	63

The results in Table 2 above demonstrate that for the ampules in Set A and in Set B, at least 595 ppm of water was sufficient to inhibit the degradation of sevoflurane. The results show no significant difference between the ampules that were shaken overnight and those that were not shaken overnight.

EXAMPLE 4

Degradation of Sevoflurane in Ampules Using Water Spiked Sevoflurane Studies at 60° C. or 40° C.

Type 1 clear glass ampules were employed to study the effect of various levels of water and temperature in inhibiting the degradation of sevoflurane. Approximately 20 mL of sevoflurane and different levels of water ranging from about 109 ppm to about 951 ppm were added to each ampule. The ampules were then flame-sealed To accelerate the degradation process, samples from each moisture level were placed at two heating conditions. Samples were placed on a 60° C. stability station for 144 hours or placed on a 40° C. stability station for 200 hours. The resulting sevoflurane in each of the samples was analyzed by gas chromatography and pH. Hexafluoroisopropyl alcohol (HFIP) and the total degradants of sevoflurane were measured The results are shown below in Table 3.

TABLE 3

Sample	Total Moisture	pH	HFIP (ppm)	Total Degradants (ppm)
Water-spiked, 60° C., 144 hrs				
1	109	0	850	474796
2	206	3.5	7	48
			8	65
3-1	303	3.5	11	68
			10	88
3-2	303	5.0	8	60
4	595	5.5	7	66
5-1	951	5.5	4	52
5-2	951	5.5	4	60
Water-spiked, 40° C., 200 hrs				
6-1	No H_2O added	0	232	102435

TABLE 3-continued

Sample	Total Moisture	pH	HFIP (ppm)	Total Degradants (ppm)
6-2	No H_2O added	2.5	24	68
7	109	3.0	40	77
8	206	5.0	7	59
9	303	5.0	6	59
10	595	6.0	6	60
11	951	6.0	5	60

The results in Table 3 demonstrate that at 40° C. for 200 hours, water levels higher than 206 ppm, inhibit the degradation of sevoflurane. For samples stored at 60° C. for 144 hours or longer, water levels higher than 303 ppm inhibit the degradation of sevoflurane. This data suggests that as the temperature increases, the amount of water required to inhibit the degradation of sevoflurane will increase.

EXAMPLE 5

Sevoflurane Degradation in Activated Type III Amber Glass Bottles

Type III amber glass bottles that were used to store degraded sevoflurane were examined. Those bottles that exhibited a significant amount of etching inside the bottle were selected. A total of ten Type HI amber glass bottles were selected. The degraded sevoflurane contained in each of these bottles was drained and the bottles were rinsed several times with non-degraded fresh sevoflurane. Approximately 100 mL of non-degraded sevoflurane containing about 20 ppm water was added to each bottle. Gas chromatography analysis for all the samples was performed at the time zero and after heating at 50° C. for 18 hours. Hexafluroisopropyl alcohol (HFIP) and dimethyleneglycol ether (P2) were measured. The results are shown in Tables 4 and 5 below.

TABLE 4

Results at Time Zero

	Degradation Products (ppm)		
Bottle Number	HFIP	P2	Total
1	124	<10	185
2	84	<10	123
3	77	<10	137
4	56	<10	89
5	144	<10	190
6	63	<10	96
7	58	<10	95
8	60	<10	102
9	51	<10	106
10	65	<10	140

TABLE 5

Results at 50° C., 18 Hours

	Degradation Products (ppm)		
Bottle Number	HFIP	P2	Total
1	1026	7938	14243
2	912	3013	6428

TABLE 5-continued

Results at 50° C., 18 Hours

Bottle Number	Degradation Products (ppm): HFIP	P2	Total
3	1160	4662	10474
4	908	3117	7381
5	907	6687	11774
6	1128	5448	11313
7	1152	2371	6695
8	1199	2925	7386
9	1560	4183	10325
10	1455	2255	6667

The results in Tables 4 and 5 show that the glass surfaces in these bottles were "activated" by degraded sevoflurane. "Activated" glass surfaces thus served as initiators for the degradation of fresh sevoflurane.

EXAMPLE 6

Additional Studies of Sevoflurane Degradation In Activated Type III Amber Glass Bottles

The extent of the degradation of sevoflurane in each of the bottles from Example 5 were quantified by gas chromatography. The ten bottles were divided into two groups, the Control Sevo Group (containing bottles 2, 3, 5, 7, 8) and the Study Sevo Group (containing Bottles 1, 4, 6, 9, 10).

All ten bottles were re-rinsed several times with non-degraded sevoflurane containing about 20 ppm of water. For the five Control Sevo Group bottles, 100 mL of sevoflurane containing about 20 ppm of water was added to each bottle. For the five Study Group bottles, 100 mL of sevoflurane containing about 400 ppm of water (spiked) was added to each bottle.

Gas chromatography for all samples was performed at time zero and after heating at 50° C. for 18 hours. Hexafluoroisopropyl alcohol (HFIP), dimethyleneglycol bishexafluoroisopropyl ether (P2) and total degradants were measured. The results are shown below in Table 6.

TABLE 6

Results at the Zero Hour and Eighteen Hours

	Degradation Products (ppm)					
	HFIP		P2		Total	
Time	0 hour	18 hour	0 hour	18 hour	0 hour	18 hour
Control Group (20 ppm water)						
2	<10	777	<10	2291	<50	5995
3	<10	790	<10	2714	<50	6552
5	11	688	<10	2446	<50	5485
7	<10	894	<10	1171	<50	4124
8	<10	824	<10	1950	<50	5139
Study Group (400) ppm water)						
1	12	605	<10	<10	<50	669
4	<10	84	<10	<10	<50	98

TABLE 6-continued

Results at the Zero Hour and Eighteen Hours

	Degradation Products (ppm)					
	HFIP		P2		Total	
Time	0 hour	18 hour	0 hour	18 hour	0 hour	18 hour
6	<10	331	<10	<10	<50	357
9	<10	294	<10	<10	<50	315
10	10	528	<10	<10	<50	577

The results in Table 6 show that at zero hour, no significant degradation of sevoflurane was observed when compared to that of the zero-hour results in Table 4. The results in Table 6 show that, in the Study Sevo Group (400 ppm water), the degradation of sevoflurane was significantly reduced. The amounts of degradants P2 (dimethyleneglycol bishexafluoroisopropyl ether) and S1 (methyleneglycol fluoromethyl hexafluoroisopropyl ether) were much less than those in Control Group 1 (20 ppm water). The HFIP concentration in the Study Sevo Group, however, was quite high and suggests that the glass surfaces were still somewhat active.

FIG. 4 shows a graphic comparison of the degradant dimethyleneglycol bishexafluoroisopropyl ether (P2) from the data in Tables 5 and 6. FIG. 5 shows a graphic comparison of the degradant methyleneglycol fluoromethyl hexafluoroisopropyl ether (S1) as it appears in Examples 5 and 6. Both FIG. 4 and FIG. 5 demonstrate that the degradation of sevoflurane is inhibited by the addition of water at 400 ppm.

EXAMPLE 7

Additional Studies of Sevoflurane Degradation in Activated Type III Amber Glass Bottles

Sevoflurane was decanted from the five bottles of the Study Sevo Group from Example 6. Each bottle was rinsed thoroughly with fresh sevoflurane. Approximately 125 mL of water-saturated sevoflurane was then put into each bottle. The five bottles were then placed on a mechanical roller for approximately two hours to allow the water to coat the activated glass surfaces. The water-saturated sevoflurane was then drained form each bottle and replaced by 100 mL of sevoflurane containing 400 (spiked) ppm of water. Gas chromatography analysis for all samples was performed after heating at 50° C. for 18 hours, 36 hours, and 178 hours. Bishexafluoroisopropyl ether (P2) and total degradants were measured. The results are shown below in Table 7.

TABLE 7

	Degradation Products (ppm)					
	HFIP		PF		Total Degradants	
Time	36 hour	178 hour	36 hour	178 hour	36 hour	178 hour
Study Group (400 ppm water)						
1	<10	16	<10	<10	<50	<50
4	<10	<10	<10	<10	<50	<50
6	<10	28	<10	<10	<50	<50
9	<10	15	<10	<10	<50	<50
10	<10	19	<10	<10	<50	<50

The results in Table 7 demonstrate that the degradation of sevoflurane was greatly inhibited by treating the activated glass surface with water saturated-sevoflurane prior to heating.

What is claimed is:

1. An anesthetic composition comprising:

a quantity of sevoflurane; and

a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

2. The composition of claim 1 wherein the Lewis acid inhibitor is water.

3. The composition of claim 2 containing at least about 0.04% w/w to about 0.14% w/w of water.

4. A method of preparing the anesthetic composition of claim 1 comprising the step of adding the Lewis acid inhibitor to said quantity of sevoflurane.

5. A method of preparing the anesthetic composition of claim 1 comprising the step of adding said quantity of sevoflurane, to the Lewis acid inhibitor.

6. A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of:

providing a quantity of sevoflurane;

providing a Lewis acid inhibitor in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol;

combining said quantity of sevoflurane and the Lewis acid inhibitor in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.

7. The method of claim 6 wherein the Lewis acid inhibitor is water.

8. The method of claim 2 wherein the amount of water added to the sevoflurane is from about 0.04% w/w to about 0.14% w/w.

9. An anesthetic composition comprising:

a quantity of sevoflurane; and

water in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane.

10. A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of:

providing a quantity of sevoflurane;

providing water in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane;

combining said quantity of sevoflurane and said water in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.

* * * * *

CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that he caused a copy of the foregoing Complaint be served via messenger this 16th day of March 2001 on:

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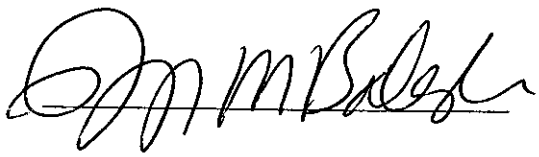

JS 44
(Rev. 11/95)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as requir by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the u of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

ABBOTT LABORATORIES
CENTRAL GLASS CO., LTD.

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____
(EXCEPT IN U.S. PLAINTIFF CASES)

JUDGE RONALD GUZMAN

DEFENDANTS

BAXTER PHARMACEUTICAL PRODUCTS
BAXTER HEALTHCARE CORP.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT LAKE COUNTY
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

MAGISTRATE JUDGE ASHMAN

SEE ATTACHMENT

ATTORNEYS (IF KNOWN)

01C1867

II. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINT AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PTF	DEF		PTF	DE
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐

IV. ORIGIN *(PLACE AN "X" IN ONE BOX ONLY)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to Distr Judge from Magistrate Judgment

V. NATURE OF SUIT *(PLACE AN "X" IN ONE BOX ONLY)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury – Med. Malpractice
- ☐ 365 Personal Injury – Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS – Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determinati Under Equal Access to Jus
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

PATENT INFRINGEMENT ACTION PURSUANT TO 35 U.S.C. § 271

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complai **JURY DEMAND:** ☒ YES ☐ NO

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE RONALD GUZMAN DOCKET NUMBER 00C5939

DATE 3/16/01 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

ATTACHMENT TO A CIVIL COVER SHEET

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Eastern Division

JUDGE RONALD GUZMAN

01C1867

MAGISTRATE JUDGE ASHMAN

In the Matter of

ABBOTT LABORATORIES
CENTRAL GLASS CO., LTD.
v.
BAXTER PHARMACEUTICAL PRODUCTS
BAXTER HEALTHCARE CORP.

Case Number: 01C 1867

DOCKETED

MAR 19 2001

APPEARANCES ARE HEREBY FILED BY THE UNDERSIGNED AS ATTORNEY(S) FOR:

ABBOTT LABORATORIES AND CENTRAL GLASS CO., LTD.

FILED
01 MAR 9
U.S. DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Eastern Division JUDGE RONALD GUZMAN

In the Matter of

ABBOTT LABORATORIES
CENTRAL GLASS CO., LTD.
v.
BAXTER PHARMACEUTICAL PRODUCTS
BAXTER HEALTHCARE CORP.

MAGISTRATE JUDGE ASHMAN
Case Number: 01C 1867

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	DESIGNATED AS LOCAL COUNSEL? YES ☐ NO ☒
(C)	**(D)**
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FIRM	FIRM
STREET ADDRESS	STREET ADDRESS
CITY/STATE/ZIP	CITY/STATE/ZIP
TELEPHONE NUMBER	TELEPHONE NUMBER
IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE)	IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE)
MEMBER OF TRIAL BAR? YES ☐ NO ☐	MEMBER OF TRIAL BAR? YES ☐ NO ☐
TRIAL ATTORNEY? YES ☐ NO ☐	TRIAL ATTORNEY? YES ☐ NO ☐
DESIGNATED AS LOCAL COUNSEL? YES ☐ NO ☐	DESIGNATED AS LOCAL COUNSEL? YES ☐ NO ☐